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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,941	10/25/2005	Dirk Wybe Grijma	5100-000015/US	9691
30593 7590 06/27/2008 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195				
EXAMINER MCCLENDON, SANZA L.				
ART UNIT		PAPER NUMBER		
1796				
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06/27/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,941

Applicant(s)

GRIJPMMA ET AL.

Examiner

Sanza L. McClendon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-21, and 23-24 is/are rejected.
- 7) ☒ Claim(s) 5-7 & 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In response to the Amendment received on 3/05/2008, the examiner has carefully considered the amendments. The examiner acknowledges the copies of the certified translations of the foreign priority documents for the International Bureau.

Response to Arguments

2. Applicant's arguments, see Remarks/Translated Priority Papers, filed 3/05/2008, with respect to claims 1-2 and 8-24 have been fully considered and are persuasive. The rejection of claims 1-2 and 8-24 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as being unpatentable over **Ana Paula Pêgo et al** (*Polymer, Volume 44, Issue 21, October 2003, Pages 6495-6504*) has been withdrawn. The rejection of claims 1-4, 8-911, 15-21 and 23-24 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as being unpatentable over Huang et al (7,037,983 and 2003/0232929) has been withdrawn. The rejection of claims 1, 3-9, 18, 21 and 23-24 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as being unpatentable over Amsden et al (2003/010524 and 6,984,393) has been withdrawn. The rejection of claims 1, 3-8, 12-14, 16-18, 23-24 under 35 USC 102(b/e) as being anticipated by or, in the alternative, under 35 USC 103(a) as being unpatentable over Pathak (2003/0077272; 2002/0114775; 7,211,651; 7,057,019; and 6,887,974) has been withdrawn.

3. Applicant's arguments filed 3/05/2008 with regard to Ritter et al (4,496,446) and Roby et al (5,889,075) have been fully considered but they are not persuasive. Regarding Ritter et al, applicant argues that Ritter sets forth TMC co-polymers that do not correspond to the TMC copolymers intended for the instantly claimed invention. Applicant is reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention. The TMC copolymers as found in Ritter et al read on the instantly claimed TMC co-polymers as instantly written. Thus the rejection still stands.

4. Regarding Roby et al, applicant argues that Roby et al sets forth TMC co-polymers that do not correspond to the TMC copolymers intended for the instantly claimed invention. Applicant is reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention. The TMC copolymers as found in Roby et al read on the instantly claimed TMC co-polymers as instantly written. Additionally it is argued that Roby et al discloses terpolymers not copolymers. This is not convincing since a co-polymer is defined as having two or more types of monomers. Additionally this appears to be a block copolymer wherein block A comprises a polymer formed from TMC with a B block formed from a different type of monomers. Thus the teaching of Roby et al fit the broadest reasonable definition according to the claimed language as written. Thus the rejection still stands.

Claim Rejections - 35 USC § 102/35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ritter et al (4, 496,446).

Ritter et al teaches irradiating structural surgical elements, such as an anastomosis ring device, with gamma radiation to improve properties such as initial strength, in vivo strength and degradation loss rate of said strength properties. Said surgical elements are made of bioabsorbable polymers, such as polyglycolides and copolymers of glycolides with trimethylene carbonate—column 10, line 48. Ritter et al discloses the use of gamma radiation dosages of up to 10 Mrad (100 kGy). In addition, Ritter et al teaching ethylene oxide sterilization of said structural surgical devices—see column 4, lines 35 to 40. Regarding the properties as found in claims 12-14, Ritter et al discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al. In the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

8. Claims 1-4, 8-14, 15-21 and 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roby et al (5,889,075).

Roby et al sets forth irradiated surgical sutures and methods of making them. Said surgical sutures are fabricated from a copolymer of dioxanone, trimethylene carbonate, and glycolide, which is treated with gamma irradiation to enhance the properties. Said copolymers can be arranged in sequences as found in columns 2, lines 59-68 to column 3, and lines 1-14. The irradiation treatment is from a total dose rate from about 2 to about 12 Mrad in an inert atmosphere while under vacuum. Thus the examiner deems claims 10 and 11 are envisioned in the reference. Regarding the properties as found in claims 12-14, Roby et al discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al. In the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Allowable Subject Matter

9. Claims 5-7 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L. McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sanza L McClendon/
Primary Examiner
Art Unit 1796

SMc

